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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/801,164	03/07/2001	Norbert W. Bischofberger	172.2USDC2	7772
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Max D. Hensley Gilead Sciences, Inc. 333 Lakeside Drive			EXAMINER	
			LUKTON, DAVID	
Foster City, CA 94404			ART UNIT	PAPER NUMBER
			1653	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

Applicant(s)

09/801,164

Bischofberger

Examiner

Office Action Summary

David Lukton

Art Unit **1653**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____3 ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on Jan 14, 2002 2b) X This action is non-final. This action is FINAL. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 52 4a) Of the above, claim(s) ______ is/are withdrawn from consideration. is/are allowed. 5) Claim(s) 6) X Claim(s) 52 is/are objected to. 7) Claim(s) ______ are subject to restriction and/or election requirement. Claims ___ **Application Papers** The specification is objected to by the Examiner. The drawing(s) filed on ______ is/are objected to by the Examiner. 10) 11) The proposed drawing correction filed on is: a) approved b) disapproved. The oath or declaration is objected to by the Examiner. 12) Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) All b) Some* c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 2. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Interview Summary (PTO-413) Paper No(s). Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 191 Notice of Informal Patent Application (PTO-152) 161 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 201 Other

Applicants' species election is acknowledged. (The compound in which "R" is phenyl, "R³⁴" is hydrogen, and "B" is cytosinyl).

*

The abstract should be revised to reflect the subject matter now claimed. It is suggested that the structural formula be provided in the abstract. (However, space limitations will preclude fully defining the substituent variables).

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It does not appear that applicants have shown antiviral activity for any of the compounds falling within the scope of claim 52. The data on pages 108 and 109 is noted, but it does not appear that any of these compounds falls within the scope of claim 52. Applicants are requested to point to the page and line number where data in support of the genus of claim

52 can be found.

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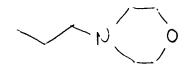
Claim 52 is rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Currently, the Markush format is not proper. For example, the following is recited: "R independently is phenyl, 2- and 3- pyrrolyl, 2- and 3-thienyl, ...etc."

 The conventional "selected from the group consisting of" language should be used.
- Claim 52 recites that variable "R" can be aryloxyethyl, and that this particular aryl group can contain 6-9 carbon atoms. Clearly, if the aryl group contains 6 carbon atoms, it is phenyl. However, it is not at all clear which aryl group contain contain only seven carbons, only eight carbons, or only nine carbons. Of course, one can have alkylaryl groups, or indan, or other groups containing sp³-hybridized carbons, or heteroaryl groups. But these are not appropriately termed "aryl" groups.
- In claim 52, the following Markush Group member is recited in two different places: "2-, 3-, and 4-haloalkylphenyl"

 However, it would appear that one such recitation is sufficient. In addition, "phenyl" is recited twice.
- Claim 52 recites that "R" can be N-ethylmorpholino. This is then followed by two alternative representations of the moiety in question. However, these alternative respresentations tend to disrupt the flow of information, and moreover, the size of the parenthesis is not commensurate with the size of the structure provided. What is suggested is to delete the two alternative representations of "N-ethylmorpholino", and then to add the following claim:

The compound according to claim 52 wherein R is



• The substituent following N-ethylmorpholino is "adamantoyl oxymethyl". However, this should probably be one word, rather than two (adamantoyloxymethyl). In addition, it is very unclear what is intended with regard to the next few substituents following the term "adamantoyl oxymethyl". There is a structure that contains an adamantyl group. In applicants opinion, which of the names applied (if any) corresponds to this structure? It would appear that either of the following would constitute more suitable nomenclature:

1-adamantane-carbonyloxymethyleneoxymethyl-1-adamantane carboxylic acid, methoxymethylenoxy ester

There is also the matter of the molecular "bookeeping" with respect to the oxygen atom that "R" is bonded to.
Is the oxygen atom being accounted for twice?

- Claim 52 recites the following as among the possibilities for "R": "2-,3- and 4-acetylphenyl"

 Here, there should be a space between the "2" and the "3".
- Claim 52 recites that "R independently is" one of the following:

$$-O-C_{10}H_6-O-$$

 $-O-C_6H_4-C_6H_4-O-$

However, in this case, "R" is not "independently" either of these, moreover, it is not clear how one has **two** separate "R" groups, as mandated by the claim. In addition, it appears that the oxygen atoms are accounted for twice; if not, then applicants are attempting to claim a very unstable bis-arylhydroperoxide. An independent claim should be created for these two substituent possibilities (This would not result in any loss of scope, since if "R" is either of these, "R" cannot be anything else).

• Though not an absolute requirement, clarity would be enhanced if three new substitutent variables were created (e.g., X1, X2, X3), and "X1" could then encompass the aryl and substituted aryl substituents, "X2" could then encompass the heteroaryl substituents, and "X3" could encompass the alkyl and substituted alkyl substituents, i.e., the following

A compound of formula 2

wherein each R is independently selected from the group consisting of X1, X2, X3, R^5 , NHR^{6A} and $N(R^{6A})_2$, and wherein

X1 is selected from the group consisting of phenyl, alkoxyphenyl, carboalkoxyphenyl, acetylphenyl...[etc.];

X2 is selected from the group consisting of pyrrolyl, thienyl, imidazolyl, oxazolyl, isoxazolyl, thiazolyl, pyrazolyl, pyridinyl, pyrimidinyl ...[etc.];

X3 is selected from the group consisting of ethyl, t-butyl, isopropyl, adamantoyloxymethyl, CH_2 - CH_2 Cl, CH_2 CF₃... [etc.];

Claim 52 recites that R^{6A} is a C₁₋₂₀-alkyl group which is substituted by a "substitutent" that is a single nitrogen or oxygen atom. What is meant by this? Does this mean that a carbon atom within the alkyl chain is substituted with a nitrogen atom or an oxygen atom...? If so, this should be made clear.

Applicants are advised that the specification will be (but has not yet been) amended at page 97, line 22 to reflect the abandoned status of serial number 08/050,698).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800

S. Keller